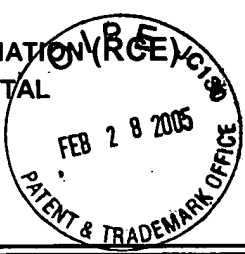


174

RCE

<b>REQUEST FOR CONTINUED EXAMINATION TRANSMITTAL</b>  Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	10/014,977
	Filing Date	12/10/2001
	First Named Inventor	Webber
	Group Are Unit	3736
	Examiner Name	Nasser, R.
	Attorney Docket Number	147117-100002



**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**  
 Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

- a. ☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
  - i. ☒ Consider the arguments in the Appeal Brief or Reply Brief previously filed on March 4, 2004
  - ii. ☒ Other Amendment After Final filed on January 9, 2004
- b. ☒ Enclosed
  - i. ☒ Amendment/Reply
  - ii. ☐ Affidavit(s)/Declarations(s)
  - iii. ☒ Information Disclosure Statement (IDS)
  - iv. ☐ Other \_\_\_\_\_

2. **Miscellaneous**

Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a

- a. ☐ period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required.)
- b. ☐ Other \_\_\_\_\_

3. **Fees**

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

- a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 50-2468.
  - i. ☒ RCE fee required under 37 CFR § 1.17(e)
  - ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
  - iii. ☐ Other: \_\_\_\_\_
- b. ☐ Check in the amount of \$ \_\_\_\_\_ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

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**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

OFFICE OF PETITIONS

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

Name (Print/Type)	Coe A. Bloomberg	Registration No. (Attorney/Agent)	26,605
Signature	<i>Coe A. Bloomberg</i>	Date	February 23, 2005

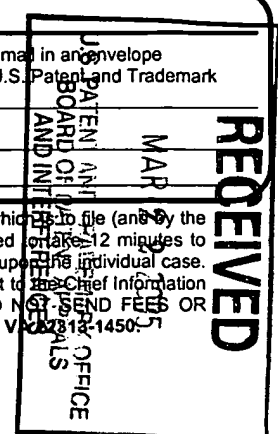
**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

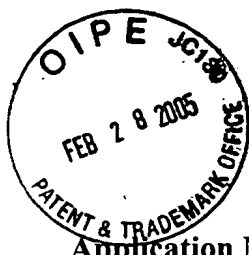
Name (Print/Type)	Fay Lum-Lee	Date	February 23, 2005
Signature	<i>Fay Lum-Lee</i>		

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the publish which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 and select option 2.



Patent  
147117-100002



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/014,977

Confirmation No. 3321

Applicant: Michael Webber

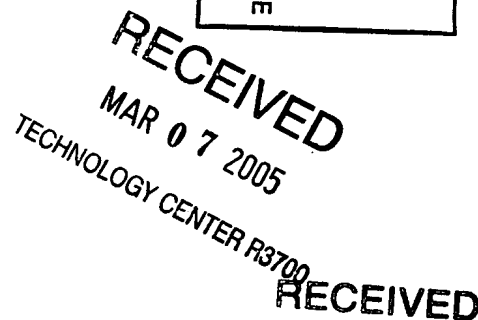
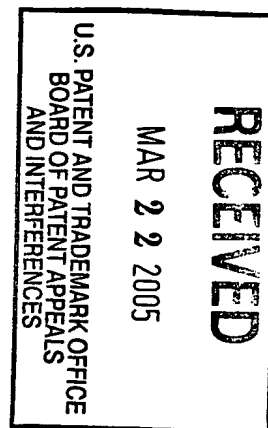
Filed: December 10, 2001

TC/AU: 3736

Examiner: R. Nasser

Docket No. 147117-100002

Customer No. 34026



MAR 07 2005

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR CONTINUED EXAMINATION (RCE)  
REPLY UNDER 37 C.F.R. 1.111**

OFFICE OF PETITIONS

Applicant here submits the following arguments made in an Appeal Brief filed on March 3, 2004 pursuant to 37 C.F.R. § 706.07(h), first and second paragraphs.

The threshold concentration is the separation point between non-alveolar breath and alveolar breath (see Figure 2). As stated at page 9, claims 18-21, the threshold varies from person to person,

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(37 C.F.R. §1.8a)**

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

February 23, 2005  
Date of Deposit  
LAI-2175121v1

Fay Lum-Lee  
Name of Person Mailing Paper

*Fay Lum-Lee*  
Signature of Person Mailing Paper

and for CO<sub>2</sub> ranges from 3.5 to 5.5 percent. Claims 13, 25 and 36 describe a method where the threshold for measuring a second gas concentration is carried out when the first gas concentration is at least 3.5 percent. Claims 6, 14, 26 and 37 describe a method where the threshold is at least 4.5 percent. Thus, both of these thresholds are within the normal CO<sub>2</sub> threshold range. And these claimed preferred thresholds of 3.5 and 4.5 percent are clearly supported by the specification. See page 6, lines 5-7:

Where carbon dioxide is the first component, the threshold concentration preferably includes relative concentrations equal to or greater than 3.5%, and more preferably equal to or greater than 4.5%.

At pages 11-12 of the specification, paragraph 0032 describes that a threshold concentration level may be static, where the threshold is set and left at that level for subsequent breaths, or variable dependent on the concentration of the concentration profile of a previously expired breath. An example of a variable threshold is given where the highest concentration of CO<sub>2</sub> was measured at 5.5%, and the threshold was adjusted to 5.0%.

The Examiner states that the specification lacks support for claims 5-6, 13-14, 25-26, and 36-37 because:

In the instance where, *for some reason*, the previous breath's highest level was 3% of [sic] below or the lowest level was 2.5% or below, the updated threshold would be 3% or below. [Emphasis added.]

As previously pointed out, the Appellant's specification has disclosure support for thresholds of 3.5% and 4.5% at page 6, lines 5-7. 35 U.S.C. § 112, first paragraph, requires that the specification describe the invention. The invention of claims 5-6, 13-14, 25-26 and 36-37 is described in Appellant's disclosure. A threshold of 3.0 or below, referred to by the Examiner, is not claimed by claims 5-6, 13-14, 25-26 and 36-37. It is submitted that there is support for the invention of claims 5-6, 13-14, 25-26 and 36-37 as required by 35 U.S.C. § 112, first paragraph.

Moreover, it is submitted the Examiner's hypothetical factual situation is unjustified. Given that the normal threshold of CO<sub>2</sub> concentration between non-alveolar breath and alveolar is 3.5 to 5.5%, the highest CO<sub>2</sub> level is, by definition, above the threshold, and thus must be higher than 3.5%. So, a threshold of 3% or below proposed as a possibility by the Examiner would be well outside the normal range. It is submitted that not only is the Examiner's position unsupported by the legal requirements of 35 U.S.C. § 112, it is based on a hypothetical that is contrary to the generally accepted biology that demonstrates that the highest level of CO<sub>2</sub> is above the 3.5 to 4.5% threshold level of concentration.

**A. 35 U.S.C. § 103 Rejection of All Claims**

All of the claims have been rejected on obvious grounds based on the combination of a number of references. For example, claims 30 and 41 stand rejected as obvious based on combining the following five references:

1. Gustafsson et al., U.S. Patent No. 6,038,913 combined with
2. Kiefer, U.S. Patent No. 3,830,630 combined with
3. Forrester et al., U.S. Patent No. 5,376,555 combined with
4. Culver, U.S. Patent No. 5,445,160 combined with
5. Grafton, U.S. Patent No. 6,192,261.

It is submitted that the fact that the Examiner relies on a combination of five references is itself indicative of nonobviousness.

It is believed that the Examiner has been forced to rely on so many references, because each individual reference has an admitted lack of teaching of critical features of Appellant's claimed invention. For example,

- Gustafsson “does not teach a method of ensuring that only alveolar breath components are measured” (October 9, 2003 Final Rejection, sentence bridging page 4 and 5).
- The Kiefer and Forrester combination “does not base the trigger threshold on previous measurements” (October 9, 2003 Final Rejection, page 4, lines 3-4).
- Kiefer “does not have optical or spectrophotometric measurements” (June 5, 2003 Office Action, page 2, last paragraph).
- The Forrester and Kiefer combination “does not multiplex the optical signals” (June 5, 2003 Office Action, page 3, lines 3-4).

In addition to these admitted deficiencies in the cited prior art, it is not disputed that:

- Culver does not measure two components of breath, it simply detects a gas in breath to determine if the patient has stopped breathing.
- Grafton does not measure two components of breath either. Indeed, it does not analyze **any** gas in breath, and is cited by the Examiner to show a multiplexer.

While there is a single basis for an obvious rejection of claims 30 and 41, other rejected claims are rejected on alternate theories and various combinations of the five references cited above. For example, claims 20-22, 24-26, 29-30, 32-34, 36-37, 39 and 41-42 were rejected under 35 U.S.C. § 103 based on four different combinations of references:

- (a) Kiefer plus Forrester plus Culver;
- (b) Kiefer plus Forrester plus Culver plus Grafton;
- (c) Gustafsson plus Kiefer plus Forrester plus Culver; and
- (d) Gustafsson plus Kiefer plus Forrester plus Culver plus Grafton.

It is believed that it is not necessary to address each basis of rejection for each group of claims because all of the rejections share what is believed to be a common flaw in that they all are based on the Examiner's contention at page 4 of the October 9, 2003 Final Rejection that:

it would have been obvious to modify the above combination (Kiefer and Forrester) to update the threshold based on previous measurements in order to allow the device to be fine tuned to each patent (Culver).

There is no suggestion to make such a combination of the Kiefer, Forrester and Culver references (common to all of the Examiner's § 103 rejections). Indeed, the references teach against such combination "to update the threshold."

In Kiefer, the threshold is fixed at 4.5%:

filament 17 is **purposely designed** so that a 4-1/2% CO<sub>2</sub> content in the breath sample causes filament 17 to unbalance the bridge of which it is a part . . . . (col. 4, l. 13-15)

Thus, there is no teaching in Kiefer that the device "purposely designed" to have a fixed, static threshold of 4.5 could be modified to measure alveolar breath "based on the concentration of the first component in a previously expired breath" as disclosed and claimed by Appellant.

If the threshold were to be changed in Kiefer based on previously expelled breath, filament branch 17, specifically designed for a 4.5 threshold, would have to be removed and replaced by another filament in the electrical balance bridge capacitor between patient breaths. Stated differently, the suggested combination would render Kiefer inoperative.

Similarly, Forrester discloses a "**predetermined threshold**" (col. 5, l. 51). Forrester uses thermopile infrared detectors for measuring gas analysis, but notes that the filament sensor of Kiefer could also be used (col. 6, l. 19-23). So again, Forrester teaches a fixed predetermined threshold, and contains no suggestion that it be combined with Culver.

*In re Dembiczak*, 175 F.3d 544, 1560, 50 U.S.P.Q. 2d 1617 (Fed. Cir. 1999) involved an appeal of the rejection under § 103 of claims directed to plastic trash bags with a pumpkin face. The § 103 obviousness rejection was based on a combination of children's art references (Holiday and Shapiro) and conventional trash bag references. In reversing, the Federal Circuit noted that the portion of § 103 heading "at the time the invention was made" guards against entry into the "tempting but forbidden zone of hindsight". *Id.* at 998 (citations omitted). Specifically, the Federal Circuit noted that:

The Board's decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. . . . This reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with convention trash or lawn bags to yield the claimed invention. *Id.* at 1000.

And see, *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60 U.S.P.Q. 2d 1001 (Fed. Cir. 2001) holding that:

[I]f references taken in combination would produce a "seemingly inoperative device", we have held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness. (Citations omitted).

It is respectfully submitted that Appellant's claims have been rejected based on entry into the forbidden zone of hindsight. There is no suggestion that the references be combined, and indeed they teach against their combination.


It is submitted that the foregoing arguments respond to the outstanding Final Rejection. Attorney for applicant was confused by the Advisory Action mailed January 27, 2004 that has all of the claims listed as allowed. Upon receiving a docketing statement from the Board indicating that a reply brief and request for oral hearing were not filed (because attorney for applicant thought the

case to be allowed), attorney for applicant noticed an arrow on the Advisory Action that he now understands was meant by the Examiner to indicate the claims were not allowed. Accordingly, continued examination is requested.

Respectfully submitted

**JONES DAY**

Date: February 23, 2005

By   
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